PSJ3

Exhibit 402

From: Gray, John <jgray@hdmanet.org>
Sent: Friday, April 20, 2012 3:01 PM
To: Couch, Ken; Dale Smith; Dave Neu; Gray, John; Julian, Paul; Kaufmann, Mike; Moody, David; Scherr, Ted
Cc: Richard Frank (rfrank@ofwlaw.com)
Subject: DEA Initiatives
Attachments: DEA Options Memorandum (Jgray edits).docx

Gentlemen:

After our last teleconference call on April 6, HDMA met with legal counsel Bob Barnett and Richard Cooper of Williams & Connelly in Washington, D.C. Both attorneys were very helpful several years ago in initializing our original meetings with DEA after the first outbreak of ISO's. Given their experience and knowledge of the political and legal aspects of dealing with DEA, we updated them on the industry's recent concerns with DEA's latest efforts to thwart drug diversion and abuse. Attached is a brief summary of our discussion and conclusions with several possible courses of action HDMA could take. The entire list of ideas is not necessarily mutually exclusive, but does represent a wide range of potential actions the Association and the industry may consider in an effort to alter the present direction DEA is taking with respect to suspicious order monitoring.

I would encourage you to share these options within your companies to elicit feedback and suggestions about which, if any, of these ideas is feasible and likely to be helpful to the entire membership. My goal is to review this document at our upcoming Executive Committee meeting in San Antonio, Texas on June 10. In the meantime, please contact me if you have any questions or immediate ideas about these suggestions.

I hope you are all well.

John Gray

DRAFT – Not for Circulation External to HDMA

To: HDMA Executive Committee
From: John M. Gray
Re: Potential Approaches to Addressing DEA Enforcement Issues
Date: April 20, 2012

On April 13, HDMA staff and legal counsel met with Bob Barnett and Rich Cooper from the law firm Williams & Connolly. The purpose of the meeting was to discuss potential strategies for addressing DEA-related issues. This memo provides an overview of the meeting and the proposed recommendations moving forward.

Mr. Barnett and Mr. Cooper felt that new legislation to specifically address our concerns with DEA was highly unlikely to be successful due to limited momentum in that direction. Moreover, elected officials tend to steer away from controversy during an election year. They felt that we may be better off averting DEA actions by taking even stronger compliance measures. Also, if DEA rebuffs these measures or takes action after their adoption, we would be better positioned to seek the Congressional support.

Three key suggestions came out of the meeting and are listed below. It was suggested that we take these ideas directly to DEA for consideration pending HDMA member approval.

1. Create a product order database (ARCOS data fall-back)

Establish an HDMA database containing information on particular customer quantities ordered. The database would be similar to ARCOS but contain some different elements (e.g., Schedule IV benzodiazepines which are abused synergistically with ARCOS-reportable drugs). It would not identify distributors or terms of sale but would disclose customers and amounts of product shipped. HDMA members would voluntarily provide the data, and the database would be accessible only to those participants (and, perhaps, DEA) for developing comparisons and verifying customers' representations.

Qualifiers: The specifications of such a database need careful anti-trust review. It may be advisable for HDMA to seek a business review by the Antitrust Division of the U.S. Department of Justice (DOJ).

Pro:

- Participants have more control over data availability, and it would be more timely than ARCOS.
- Distributors would be able to determine total volume of controlled substances purchases on a registrant by registrant basis.
- More data may also help participants if they must respond to court orders or other investigations.

Con:

- Could be very expensive, given the anticipated volume.
- The impact on nationwide ordering patterns of non-HDMA distributors or non-participants, which could be substantial, would remain unknown.
- Even if we have substantial participation, DEA may assert that the data are "skewed" merely because it doesn't represent 100% of orders and that its use does not provide a safe harbor for distributors' business practices or in any way affect DEA's enforcement discretion.

2. Algorithm to identify suspicious customers and establish "thresholds"

Develop a system/computer program to enhance identification of "suspicious" customers. The program would take account of each customer's size, patient demographics, proximity to hospitals, nursing homes, and other relevant factors. Customers would be required to submit the information; some checking and routine updating would be performed. The program would assign each customer a "threshold" number for distributor use in assessing number of controlled substances ordered. HDMA members could choose individually to sell only to

customers within this program. The program adds to, or substitutes for, current order quantity assessments.

Qualifiers: Needs careful anti-trust review. Antitrust Division acceptance that such a system will not violate anti-trust laws appears necessary. Timely, complete customer participation submission will be important for success. Option # 1 appears to be a prerequisite for this option.

Pro:
- Standardizing threshold calculation may simplify and enhance compliance.
- Even if DEA doesn't "approve" it, our members may be in a stronger position (*e.g.*, in registration suspension proceedings) if members use a standardized approach.
- More data may help balance out the weaknesses of each distributor doing it on their own with less data, including when evaluating distribution to individual practitioners making very small product orders.

Con:
- Could be very expensive and feasibility may not be apparent until after attempting development.
- If DEA asserts that that the algorithm is invalid if there is not 100% participation (including participation by non-HDMA members) its value for preventing DEA actions against a distributor may be limited.
- Customers may object to the program and/or it could be difficult to obtain their participation.

3. Establish a Private, Independent Third (3rd) Party Audit Program

The 3rd party would audit HDMA members' compliance at the member's request and pursuant to DEA-reviewed protocols. Report results would be provided only to the companies audited; those companies could share the results with DEA if they decide to do so.

Pro:
- Gives distributors a greater level of assurance that their order monitoring is on the right track.
- Could help standardize order monitoring, potentially lessening individual vulnerability.
- DEA would never give "safe harbor" but if they agreed to the above, it could be the next best thing.

Con:
- No guarantee that DEA will agree to refrain from enforcement initiatives.
- Places HDMA in effective competition with existing third-party regulatory consultants and merely duplicative for those HDMA members which have already sought 3rd party input.
- Expense is unknown.

Other potential actions:
- Update the HDMA Industry Compliance Guidelines (ICG) – originally published in 2008.
- Re-file the HDMA Amicus Brief in the CAH v. DEA appellate case.
- Encourage Members of Congress to send inquiries to DEA on the status of answers to HDMA's June 2011 questions on suspicious order monitoring programs.
- Work with the National Governors Association (NGA) Prescription Drug Abuse Reduction Policy Academy to create greater understanding of distributor's efforts to prevent diversion and develop best practices for States to utilize.
- Seek guidance from a well-respected public relations firm to improve industry image.
- Petition DEA to put their expectations into a regulation. If they do, we could submit our views via the public comment process and DEA must respond. More importantly, a final rule would provide clarity. If they do not, it could give us considerable political leverage.
- Develop a legal journal article (e.g., Washington Legal Foundation) on the ambiguity of DEA expectations and diversion prevention tactics. A Congressional hearing may be more effective in this regard but would unlikely to happen prior to the 2012 elections.